EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE

STATE FARM FIRE AND CASUALTY COMPANY,	)	
Plaintiff,	)	
v.	)	
SPECIALTY SURGERY CENTER, PLLC, KENNETH R. LISTER, M.D., ELIZABETH BRAY, PEGGY B. BUMGARNER, ROGER D. BUMGARNER, WILMA S. CARTER, LAWRENCE CARTER, JUDY COLLINS, WANDA J. COX, PERRY COX, WANDA J. DINGESS, BOBBY A. FOSTER, DOROTHY A. FUELLING, RICHARD E. FUELLING, CRAIG E. WEAVER, Administrator Ad Litem of the Estate of PATRICIA A. GAMBACCINI, DANETTE GRAHAM, GEORGEANNE HUBBARD, LINDA JACKSON, JOHN JOHNSON, EDNA S. KEYES, WILLIAM LAPISKA, SHERRY A. MCDAVID, next of kin of DONALD F. MCDAVID, DARWIN L. NEALON, Administrator of the Estate of DALLAS RAY NEALON, JOCELYN KAE NORRIS, JAMES PALMER, MICHELLE PALMER, WANDA L. REED, J.E. REED, JANICE K. RHIND, CHRISTOPHER G. RHIND, SHIRLEY SAVERCOOL, PAULA K. SMITH, JIM F. SMITH, and DALE WILLIS,	)	**Case No. 2:15-cv-00026** **Chief Dist. Judge Kevin Sharp** **Magistrate Judge Joe Brown**
Defendants.	)	

[PROPOSED]
ORDER CERTIFYING QUESTIONS OF LAW TO TENNESSEE SUPREME COURT UNDER TENNESSEE SUPREME COURT RULE 23

The United States District Court for the Middle District of Tennessee certifies the following questions to the Supreme Court of Tennessee under Tennessee Supreme Court Rule 23.

(A) The style of the case

The style of the case is in the caption of this Order.

(B) A statement of facts showing the nature of the case, the circumstances out of which the questions of law arise, the questions of law to be answered, and any other information the certifying court deems relevant to the questions of law to be answered.

1. Nature of the case

General background

The unresolved Tennessee state law issues for the Tennessee Supreme Court's consideration arise from claims asserted in underlying tort litigation related to the 2012 fungal meningitis outbreak. In this declaratory judgment action, the Insurer (State Farm) sues the Insureds (Specialty Surgery Center, PLLC and Kenneth Lister, MD) and former patients ("Individual Tort Victim Defendants" or "ITV Defendants"). The Insurer seeks a declaration that it does not owe the Insureds a defense or indemnity coverage in the tort suits brought by the ITV Defendants against the Insureds.

The ITV Defendants are former patients of the Insured health care providers asserting injuries from the 2012 fungal meningitis outbreak. These lawsuits, along with scores of others against health care providers around the country, have been consolidated in multi-district litigation in the United States District Court for the District of Massachusetts.[1] One of the claims the ITV Defendants make against Dr. Lister and Specialty Surgery Center ("SSC") in the underlying tort suits is that the Insured health care providers are strictly liable under Tennessee's Product Liability Act, Tennessee Code Annotated § 29-28-101, *et seq.*, as "sellers" of contaminated medication furnished to the ITV Defendants as a component of health care services.

Insurer's position in declaratory judgment action

State Farm's position is two-fold: First, the ITV Defendants cannot, as a matter of law, maintain a cause of action for product liability against SSC or Dr. Lister related to the outbreak. Second, if the Court rules that the product liability claim is not viable as a matter of law, the only remaining viable claims against SSC and Dr. Lister in the underlying tort suits are for professional health care liability, specifically excluded from coverage under the applicable insurance policy.[2]

State Farm requests that the Middle District of Tennessee declare that (1) the ITV Defendants cannot, as a matter of law, pursue a claim of strict product liability against the Insureds arising from the fungal meningitis outbreak; and (2) because the product liability claim is not legally viable, State Farm has no duty to provide a defense or indemnity coverage to the Insureds.

[1] U.S. District Court, Massachusetts, MDL No. 2419 // Dkt. No 1:13-md-2419 (RWZ).
[2] This coverage suit hinges on the viability of the ITV Defendants' product liability claim against SSC and Dr. Lister. If it is not viable, State Farm's policy does not cover the claims.

2. Circumstances out of which the questions of law arise

In the summer 2012, New England Compounding Center ("NECC") – a compounding pharmacy in Massachusetts – produced three batches of preservative-free methylprednisolone acetate ("MPA"). During production, the MPA was contaminated with a fungus. NECC shipped contaminated vials to health care providers across the country, including three (3) clinics in Tennessee, one of which was SSC.

Dr. Lister and other physicians across the country injected the MPA supplied by NECC in individual, sealed vials, during procedures known as epidural steroid injections ("ESIs"), unaware that the MPA was contaminated. Hundreds of patients in multiple states filed suit. Twenty-four (24) lawsuits were filed against SSC and Dr. Lister. All the federal fungal meningitis lawsuits, including those against SSC and Dr. Lister, have been consolidated for pretrial proceedings in multi-district litigation pending in the U.S. District Court for the District of Massachusetts.

NECC (the manufacturer of the medicine) filed a petition in bankruptcy in U.S. Bankruptcy Court on December 21, 2012. The Tennessee Product Liability Act of 1978 permits plaintiffs to pursue a claim for strict liability in tort against the seller in the chain of distribution of a good in only limited circumstances, including when the manufacturer is bankrupt.[3] In the underlying complaints against SSC and Dr. Lister, the ITV Defendants assert that SSC and Dr. Lister acted as "sellers" of the MPA for purposes of the Tennessee Product Liability Act when Dr. Lister injected the medicine into the ITV Defendants in 2012.[4] SSC and Dr. Lister dispute that they "sold" the medication and

[3] TENN. CODE ANN. §§ 29-28-102, -106.

[4] SSC and Dr. Lister moved to dismiss the product claims. The Massachusetts District Court denied the motion but noted on several occasions that there is no Tennessee law addressing whether a health care provider can be considered a seller of medication used incidental to health care services, exposing the

instead assert they used it only incidental to the delivery of professional health care services.

State Farm issued a commercial liability policy and a commercial liability umbrella policy to SSC and Dr. Lister that were in effect at the time of the injections in 2012. The parties agree that there is no specific exclusion in State Farm's policy for claims grounded in "strict product liability" against SSC and Dr. Lister. However, State Farm asserts that the product liability claim is not viable as a matter of law, and, if the product liability claim in the underlying complaints is not viable, State Farm should not be obligated to provide a defense and coverage.[5]

State Farm and the Insured health care providers aver that the ITV Defendants cannot maintain a strict product liability cause of action for two (2) principal reasons. First, they assert that the claims against the Insureds are health care liability actions governed by Tennessee's Health Care Liability Act ("HCLA")[6], which is the ITV Defendants' exclusive substantive remedy on these facts. Second, they assert that SSC was not acting as a "seller" under Tennessee's Product Liability Act.[7]

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health care provider to strict product liability. *See* Order on Global Motion to Dismiss, August 29, 2014, 2014 WL 4322409, at *14-*15 ("The Tennessee Clinic Defendants acknowledge that Tennessee has not specifically addressed whether health care providers can be held strictly liable as sellers…This court's case law research did not unearth any Tennessee cases in which products liability claims were successfully brought against health care providers, nor any cases indicating that health care providers were categorically not sellers or could not be sued under the [Tennessee Product Liability Act]….As of the date of this opinion, there are no cases dealing with the interaction of products liability claims with the [Tennessee Health Care Liability Act]").

[5] An answer on the issue of the viability of the product liability claim will resolve all (or virtually all) of the issues in the declaratory judgment action in front of this Court. In the MDL, the Intervenor Plaintiffs (Plaintiffs with suits against another Tennessee clinic who purchased and administered MPA from NECC, Saint Thomas Outpatient Neurosurgical Center, LLC) have moved for summary judgment on the same issue. Thus, in addition to resolving the issues in the declaratory judgment action, answering this question will likely resolve the same issue in the MDL.

[6] TENN. CODE ANN. § 29-26-101, *et seq.*

[7] TENN. CODE ANN. § 29-28-101, *et seq.*

3. Operative undisputed facts

The following material facts are undisputed for purposes of deciding these legal questions:

1. This declaratory judgment action follows tort lawsuits arising from the 2012 outbreak of fungal meningitis and fungal infection caused by three (3) batches of preservative-free methylprednisolone acetate compounded and sold by NECC from May 2012 through September 2012.

2. NECC was a compounding pharmacy located in Massachusetts. It was licensed as a pharmacy in Massachusetts, in Tennessee pursuant to Title 63 of the Tennessee Code, and in every other state in the union.

3. MPA is a steroid commonly used to treat chronic back or neck pain. During an epidural steroid injection, the MPA is injected into the epidural space with x-ray guidance. The medication reduces swelling and inflammation of the nerves and tissue surrounding the spine, relieving pain.

4. In 2012, SSC was an accredited ambulatory surgery center in Crossville, Tennessee, licensed pursuant to Title 68 of the Tennessee Code.[8]

5. Dr. Lister is an anesthesiologist licensed pursuant to Title 63 of the Tennessee Code. He was a member of SSC in 2012.

6. The ITV Defendants sought treatment for back and neck pain from SSC and Dr. Lister.

7. SSC procured MPA from NECC for Dr. Lister to use at SSC when treating patients.

8. SSC began purchasing MPA from NECC in July 2012 after Dr. Lister became concerned about possible adverse patient reactions from preservatives present in the brand-name version of the medication, “Depo Medrol,” available commercially from Pfizer. SSC’s Director of Nursing, Jean Atkinson, RN, in consultation with Dr. Lister and SSC’s management company, made the decision to purchase a preservative-free formulation of MPA from NECC.

9. SSC paid NECC $8.00 per one milliliter vial of MPA. Dr. Lister administered one vial of MPA to a patient during an epidural steroid injection.

10. Dr. Lister performed epidural steroid injections on the ITV Defendants to treat their back and neck pain. The steroid administered during the ITV Defendants’ procedures was preservative-free MPA compounded by NECC.

[8] SSC is no longer operating.

11. Two fees were charged for the epidural steroid injections: a physician fee by Dr. Lister, and a facility fee by SSC.

12. Dr. Lister charged the ITV Defendants and/or their insurers the physician fee for his professional services during the epidural steroid injection procedures.

13. SSC charged the ITV Defendants and/or their insurers a facility fee of $1,250, which was a single, global fee for the epidural steroid injections that covered all aspects of the injection. This included:

a. The professional services of a nurse to assist Dr. Lister in performing the procedure, including administering a sedative when necessary[9];

b. The professional services of a surgical technician to assist Dr. Lister in performing the procedure, including positioning the fluoroscopy (x-ray) machine used to provide Dr. Lister with real-time images of the patient's spine during the procedure to ensure the MPA was being injected into the epidural space;

c. Use of SSC's facility, including an operating room for the procedure and a post-procedure recovery room;

d. Use of SSC's medical equipment, including the fluoroscopy machine used during the procedure and the equipment used to monitor the ITV Defendants' vital signs during the procedure;

e. The medications administered during the procedure, including, but not limited to, MPA from NECC;

f. The medical supplies used during the procedures, such as latex gloves, surgical masks, and gowns; and,

g. Administrative services such as recordkeeping, billing, and scheduling.

14. SSC was reimbursed approximately $200-$300 for the ITV Defendants' procedures.[10]

15. The majority of the ITV Defendants are Medicare beneficiaries.

16. Neither SSC nor Dr. Lister billed the ITV Defendants or their insurers separately for the MPA administered during their procedures.

[9] Some patients chose not to be sedated because they wanted to be able to drive home after the procedure and could not do so if they had been sedated.

[10] The reimbursement varied to some extent depending on the terms of the contract between SSC and the patient's insurer.

17. SSC and Dr. Lister did not collect sales tax from the ITV Defendants or their insurers for the MPA administered during the procedures.

18. The steroid administered to the ITV Defendants was later found to have been contaminated during compounding by NECC.

19. The ITV Defendants allege that the steroid caused varying degrees of injury and, in some cases, death.

20. NECC sought bankruptcy protection on December 21, 2012.

21. After NECC declared bankruptcy, the ITV Defendants filed suit against SSC and Dr. Lister alleging, among other things, that they are strictly liable as "sellers" of the MPA administered to the ITV Defendants, under Tenn. Code Ann. § 29-28-106.

22. NECC's bankruptcy plan was confirmed on May 20, 2015. The plan includes a settlement fund of approximately $200 million for the benefit of the victims of NECC's wrongdoing. The lawsuits against various clinics continue, including those against SSC and Dr. Lister.

4. Questions of law to be answered

The District Court requests that the Tennessee Supreme Court answer the following questions:

(1) Can a patient maintain a strict products liability action against an ambulatory surgery center licensed under Tennessee Code Title 68, or a physician licensed under Tennessee Code Title 63, for an injury sustained during an epidural steroid injection procedure, given the definition of a "health care liability action" under Tenn. Code Ann. § 29-26-101 and the burden of proof requirements established by Tenn. Code Ann. § 29-26-115?

(2) Is an ambulatory surgery center, licensed pursuant to Tennessee Code Title 68, "engaged in the business of selling" the steroid administered during an epidural steroid injection procedure, so as to be strictly liable as a "seller" under Tenn. Code Ann. § 29-28-106?

5. Any other information the certifying court deems relevant to the questions of law to be answered

None.

(C) The names of each of the parties

The parties are identified in the style above.

(D) The names, addresses, and telephone numbers of counsel for each party

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(E) A designation of the moving parties

The Court designates the following as the moving parties:

- State Farm Fire & Casualty Company
- Specialty Surgery Center, PLLC
- Kenneth Lister, MD.[11]

* * * * * * *

This honorable Court hereby certifies the above questions by this Order to the Tennessee Supreme Court and requests that the Tennessee Supreme Court consider them and answer them in due course.

Dated: December __, 2015

_____
KEVIN H. SHARP
CHIEF DISTRICT JUDGE
UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

[11] Given that State Farm, SSC, and Dr. Lister's interests align on the questions presented, this Court designates them as the moving parties, and respectfully recommends that they file the opening brief(s), and that the other parties to this action file the response brief. If the Tennessee Supreme Court prefers that only one party be designated, this Court suggests that State Farm be designated as the moving party.

Jointly submitted for entry,

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IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

STATE FARM FIRE AND CASUALTY COMPANY, Plaintiff, v. SPECIALTY SURGERY CENTER, PLLC, et al., Defendants.	)	Case No. 2:15-cv-00026 Chief Judge Sharp / Judge Brown

[PROPOSED] ORDER CERTIFYING A QUESTION OF STATE LAW TO THE TENNESSEE SUPREME COURT

In this case, Plaintiff State Farm Fire and Casualty Company ("State Farm") seeks a determination of its duty to defend and offer coverage to its insureds, Defendants Specialty Surgery Center, PLLC ("SSC") and Dr. Kenneth Lister, against tort claims pending in multi-district litigation in the U.S. District Court for the District of Massachusetts. The individual plaintiffs in those tort actions are also defendants here ("ITV Defendants").[1] Those underlying cases involve negligence claims and products liability claims arising out of the sale and distribution of tainted and defective steroids procured from a (now bankrupt) compounding pharmacy in Massachusetts. State Farm's complaint alleges that, based on the allegations in the Master Complaint in the MDL action, and the relevant policy language, it has no obligation to provide a defense or coverage to SSC for the MDL tort claims because health care providers can never be sellers of a defective or unreasonably dangerous product under the Tennessee Products

[1] The individually-named defendants, as listed on the Complaint, are: Elizabeth Bray, Peggy B. Bumgarner, Roger D. Bumgarner, Lawrence Carter, Wilma S. Carter, Judy Collins, Perry Cox, Wanda J. Cox, Wanda J. Dingess, Bobby A. Foster, Dorothy A. Fuelling, Richard E. Fuelling, Danette Graham, Georgeanne Hubbard, Linda Jackson, John Johnson, Edna S. Keyes, William Lapiska, Sherry A. McDavid, Darwin L. Nealon, Jocelyn Kae Norris, James Palmer, Michelle Palmer, J.E. Reed, Wanda L. Reed, Christopher G. Rhind, Janice K. Rhind, Shirley Savercool, Jim F. Smith, Paula K. Smith, Craig E. Weaver, and Dale Willis.

Liability Act ("TPLA"), Tenn. Code. § 29-28-101 *et seq.*

BACKGROUND

This case stems from a 2012 fungal meningitis catastrophe caused by contaminated injectable steroids. Plaintiffs across the country filed lawsuits against the compounding pharmacy, New England Compounding Center ("NECC"), that compounded the contaminated injectable steroid, methylprednisolone acetate ("MPA"), as well as against many of its affiliated companies, employees and vendors. Many of those suits also named the healthcare providers, including SSC and Dr. Lister, who bought contaminated MPA from NECC, sold the defective medication to patients, and injected the compounded medications into patients without using patient-specific prescriptions.

Under 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation consolidated the cases in the United States District Court for the District of Massachusetts, Case No. 13-md-02419, where they have been litigated for years. Following the catastrophe, NECC filed a Chapter 11 petition in the Bankruptcy Court for the District of Massachusetts. That court then declared NECC to be insolvent on July 24, 2013. Because the manufacturer, NECC, was judicially declared insolvent, under the TPLA "sellers" of the product can be found strictly liable for harm caused by an unreasonably dangerous or defective product. Tenn. Code. § 29-28-106.

State Farm filed this insurance coverage proceeding on April 30, 2015. The complaint argues that State Farm has no duty to defend or offer coverage because (1) the relevant insurance policies do not cover claims for bodily injury arising out of the rendering of professional treatment, specifically medical services or health services; (2) health care providers can never be sellers of a defective or unreasonably dangerous product under the TPLA; (3) by selling tainted epidural steroids, SSC and Dr. Lister engaged in the practice of pharmacy, which is not covered

under the policies; (4) the relevant insurance policies do not cover claims for bodily injury arising out exposure to fungi at the insureds' premises; (5) the relevant insurance policies do not cover claims for damages caused by treating the effects of fungi; and (6) two of the ITV Defendants only bring claims for product price refund, which is not a form of damages covered by the relevant insurance policies. Dkt. No. 1 at ¶¶ 51-57, 61-67.

On August 20, 2015, the ITV Defendants filed a motion to strike allegations in State Farm's complaint that pertain to the merits of the underlying tort cases pending in the MDL, or in the alternative to stay this case until the MDL proceedings conclude. Both State Farm and Defendants SSC and Dr. Lister opposed the motion. On September 23, 2015, Magistrate Judge Brown denied the motion to strike or stay, and ordered the parties to request that a question be certified to the Tennessee Supreme Court. On October 7, 8, and 19, 2015, three groups of plaintiffs in other MDL cases, patients of St. Thomas Outpatient Neurosurgical Center ("Saint Thomas Neurosurgical Patients Groups 1, 2, and 3," respectively), filed motions to intervene. This Court affirmed Judge Brown's order on November 3, 2015, and, the next day, granted all three motions to intervene.

STATEMENT OF RELEVANT FACTS

1. In the summer of 2012, NECC manufactured three batches of preservative-free MPA that contained deadly pathogens, including fungus. (Ex. 1, a true and correct copy of the FDA's website related to the recall of NECC.)[2] Hundreds of people across the United States contracted fungal meningitis and other fungal infections as a result of receiving injections of NECC's contaminated MPA. (Ex. 2, a true and correct copy of the Center for Disease Control's chart tracking the catastrophe.)

[2] Exhibits 4, 6, 7, 8, and 9 are subject to a protective order in the District of Massachusetts. ITV Defendants will file a motion to file those Exhibits under seal.

2. NECC was not a drug manufacturer licensed by the Food and Drug Administration ("FDA"). NECC had a pharmacist license in Massachusetts and Tennessee, but it was not licensed as a drug manufacturer, wholesaler, or distributor. (Ex. 3, A true and correct copy of the Tennessee Department of Health's listing of NECC's license; Ex. 4, Kelvas Dep., 149:14-151:12.) As a result, NECC was not subject to the FDA's robust regulatory regime governing FDA-licensed drug manufacturers. (Ex. 4, Kelvas Dep., 77:8-80:15; 107:10-109:1.)

3. MPA is a steroid commonly used to treat chronic back and neck pain, but its own package insert states that it is not recommended for epidural injections. Nevertheless, numerous patients, including patients of SSC, received epidural steroid injections of MPA manufactured by NECC. (Ex. 5, a true and correct copy of Depo-Medrol (a brand name of MPA) Product Insert.)

4. SSC is a licensed ambulatory surgery center in Crossville, Tennessee. (Ex. 6, Bowlin Dep., 19:20-20:25.) Dr. Kenneth Lister is an anesthesiologist licensed pursuant to Title 63 of the Tennessee Code who practiced medicine in 2012 at SSC. (Ex. 7, Lister Dep., 50:9-52:7 and Ex. 76.)

5. All of the ITV Defendants sought treatment at SSC for chronic pain injuries, and most of them received epidural steroid injections from Dr. Lister, purportedly to manage back pain.

6. In July of 2012, instead of purchasing MPA from a licensed FDA-regulated manufacturer, which had been SSC's practice for many years, SSC switched suppliers and began purchasing MPA from NECC. (Ex. 8, Atkinson Dep. 46:5-53:20, 66:8-75:18, and Exs. 93, 94, 99, 100.)

7. In 2012, Specialty Surgery Center had an internal policy, known as an "approved medication list," [3] with a stated objective to "provide safe effective medications to the Center's patients." (Ex. 7, Lister Dep. Ex. 91.) In 2012, MPA was not on the approved medication list, meaning that it had not undergone the safety review and approval of SSC's executive committee for use in the facility. (*Id*. and Ex. 9, Gina Calisher Dep. 229:22-236:23 and Ex. 617.) The existence of this formulary was only recently disclosed and discovery into this issue is on-going.

8. Dr. Lister and SSC never informed any of their patients that SSC switched drug suppliers or that these patients would receive drugs from a compounding pharmacy instead of an FDA-regulated drug manufacturer. Dr. Lister and SSC never informed any of their patients that Dr. Lister used an unapproved medication in his treatment of these patients. (Ex. 6, Lister Dep. 98:12-16.)

9. Before 2012, it was well-known in the medical community that drugs compounded by compounding pharmacies posed unique risks to patient safety that drugs manufactured by FDA-regulated drug manufacturers did not. (Ex. 10, Ebel Dep. 21:2-26:15, 166:22-167:25, and Exs. 279, 280.)

10. Under Tennessee law, in order to obtain drugs from a compounding pharmacy, a physician must write a patient-specific prescription for each individual patient that receives a compounded drug. (Ex. 11, Grinder Dep. 16:22-20:19, 32:7-33:16 and Ex. 526.) The purpose of these regulations is to ensure patient safety through a close, interconnected relationship between the patient receiving the drug, the pharmacist compounding the drug, and the doctor prescribing the drug. (*Id.*)

[3] Approved medication lists are sometimes referred to as "drug formularies."

11. NECC requested that SSC provide a list of patient names as part of the ordering process, claiming this was required because NECC was subject to the same regulations as "Walgreens or CVS." (Ex. 8, Atkinson Dep. 66:8-75:18 and Ex. 104.)

12. SSC never provided individual patient-specific prescriptions for patients receiving MPA from NECC. (Ex. 7, Lister Dep., 198:16-200:12 and Exs. 93 and 94.)

13. According to the Center for Disease Control, in the summer of 2012 through the fall of 2012, over 153 people in Tennessee contracted fungal infections as a result of exposure to tainted MPA from NECC. Sixteen of these individuals died. (Ex. 2.) According to the CDC, only three Tennessee healthcare facilities received tainted MPA from NECC: SSC, the Saint Thomas Outpatient Neurosurgical Center, and PCA Pain Clinic. (Ex. 2.)

14. Following the filing of thousands of lawsuits across the country and the subsequent bankruptcy petition of NECC, the United States Bankruptcy Court for the District of Massachusetts declared NECC insolvent on July 24, 2013. (*In re New England Compounding Pharm. Inc.*, Case No. 12-19882 at Dkt. No. 397.)

15. Following the order of insolvency, several patients of SSC, including the ITV Defendants, filed suit against SSC and Lister alleging, among other claims, that SSC was liable as a "seller" of the MPA sold to them under Tenn. Code. § 29-28-106.

16. SSC charged patients for the epidural and joint steroid injections performed at the facility. (Ex. 7, Lister Dep. 28:15-29:19.) The charge included the charge for the steroid product itself and the bills ultimately paid by patients, insurers, or third party payers included the charge for the steroid product. (Ex. 7, Lister Dep. 65:1-66:16.)

17. The Administrator of SSC, the person responsible for billing and collecting charges, admitted that SSC "provided epidural steroids to patients in exchange for money." (Ex. 6, Bowlin Dep. 27:14-17.)

STATEMENT OF RELEVANT FACTS CONCERNING INTERVENERS AND NON-PARTY SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER

1. Saint Thomas Outpatient Neurosurgical Center is an ambulatory surgery center located on the Saint Thomas Hospital campus in Nashville, Tennessee.

2. In 2011 and 2012, Saint Thomas Neurosurgical performed an average of 450 to 500 epidural steroid injections each month. It performed roughly 5,000 epidural steroid injections each year.

3. John Culclasure, M.D. is the Medical Director of Saint Thomas Neurosurgical. Debra Schamberg, R.N. is the Facilities Director for Saint Thomas Neurosurgical.

4. Dr. Culclasure does not receive a salary for acting as Medical Director of Saint Thomas Neurosurgical. He is paid a percentage of collections for the epidural injections that he gives. Specifically, Dr. Culclasure is paid an amount equal to sixty percent of the collections for each shot that he administers.

5. In late 2010, Saint Thomas Neurosurgical began purchasing MPA from a supplier in Nashville, Tennessee known as Clint Pharmaceuticals. The MPA that Saint Thomas Neurosurgical bought from Clint Pharmaceuticals did not come from a compounding pharmacy. Clint Pharmaceuticals only supplied steroids manufactured by FDA-regulated pharmaceutical companies. All of the MPA purchased by Saint Thomas Neurosurgical from Clint Pharmaceuticals was FDA-approved.

6. In June 2011, Saint Thomas Neurosurgical chose to stop buying FDA-approved steroids through Clint Pharmaceuticals and start buying compounded MPA from NECC. Saint

Thomas Neurosurgical made that change when Clint Pharmaceuticals increased its price for FDA-approved generic MPA from $6.49 per vial to $8.95 per vial.

7. Ms. Schamberg and Dr. Culclasure made the decision for Saint Thomas Neurosurgical to purchase MPA from NECC rather than Clint Pharmaceuticals. Emails sent and received by Ms. Schamberg demonstrate that Saint Thomas Neurosurgical switched from purchasing FDA approved steroids to purchasing compounded steroids from NECC in order to save $2.46 per vial.

8. During her deposition, Ms. Schamberg testified as follows:

Q. And St. Thomas Neurosurgical provides epidural steroids to patients in exchange for money, correct?

A. That is correct.

9. When Saint Thomas Neurosurgical administers epidural steroids to patients, it bills for those steroid injections separately from the services of the physicians who inject the medicine. Each time that Saint Thomas Neurosurgical administers an epidural steroid to a patient, it sends a separate invoice to the patient's private or public health insurer, such as Medicare or Blue Cross Blue Shield of Tennessee. Separate and apart from that invoice, Howell Allen Clinic (the neurosurgery group that owns ½ of Saint Thomas Neurosurgical) also sends an individual invoice to the patient's private or public insurer for the services of the physician who administered the injection.

10. Contracts between Saint Thomas Neurosurgical and various payers state that Saint Thomas Neurosurgical's charges specifically include drugs provided to patients.

11. After news of the fungal meningitis catastrophe became public, Saint Thomas Neurosurgical sent a letter dated October 16, 2012 to NECC stating:

> "NECC has breached the warranty of merchantability and fitness for the goods provided. The products supplied by NECC have deficit(s) that substantially impair the value, fitness and merchantability of the goods. Specifically, the below listed goods have been recalled and/or are no longer fit for use/sale due to contamination or suspected contamination. . . ."

CERTIFIED QUESTION

Whether, based on the factual allegations in the Master Complaint in the MDL Action and the foregoing policy language, State Farm is not contractually obligated by the Business Policy or the Umbrella Policy to provide coverage or defense to SSC and Dr. Lister for the MDL Action because under no set of facts can a health care provider be a "seller" of a defective or unreasonably dangerous product for purposes of imposing liability under the Tennessee Products Liability Act, Tenn. Code. § 29-28-101 *et seq.*[4]

PARTIES AND COUNSEL

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[4] *See* Dkt. No. 1, at ¶¶ 52, 62 (complaint stating State Farm's claim for why it owes no coverage to or defense against the underlying tort actions under Tennessee state law).

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[5] Saint Thomas Neurosurgical Patients Group 1 is composed of Ann Bequette and Walter L. Bequette, Jr.; Carolyn Bland and Leon Bland; Amarit K. Deol and Satnam Deol; Virginia Garland, individually and as daughter and next of kin of Effie Estalene C. Morris; Glenda J. Hurt and Robert J. Hurt; Kenneth Judd and Judy Judd; Joshua Kirkwood and Vanessa Kirkwood; Patricia Martin, individually and as daughter and next of kin of Mary Neal Martin, and Larry Martin, son of Mary Neal Martin; Frederick May and Loduska May; Basil McElwee and Carla McElwee; Clark Kenneth Osborne and Sherry Osborne; Mae L. Parman; Joseph M. Pellicone and Patricia C. Pellicone; Wayne Reed, individually, and as husband and next of kind of Diana E. Reed; Kevin R. Richards; Elfreida Wiley and Elton Lee Wiley; and Matthew Williams, individually and as son and next of kin of Earline T. Williams. Dkt. No. 78.

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[7] Saint Thomas Neurosurgical Patients Group 3 is composed of Shenia Altom; Vickie Barger; Travis Besaw; Donna Branham; Ben Bratcher; Barbara Campbell; Theresa Carroll; Billy Joe Coleman; Claudia Ellis; Danny Evans; Rosemary Ferguson; Ellen Glatman; Sammy Groves; John E. Jones; Dorris Jordan; Jon Kinsey; Charles Lankford; Lisa Maddox; Angela May; Orvil W. McWhorter; Melanie Miller; Anthony Morris; Dorothy Naseef; Larry Ken Pierce; Betty Smiley; Melanie Stinson; Peggy Sumner; Virginia Gail Swann; Blake Taylor; Rondal Turner; Gary Wayne Waddey; and Krissy Wilkinson. Dkt. Nos. 88 & 92.

The Court designates State Farm, SSC, and Dr. Lister as the moving parties for purposes of certification.

Under § 4 of Tennessee Supreme Court Rule 23, the Clerk of the Court is directed to serve copies of this Certification Order upon all counsel of record in this case and file with the clerk of the Supreme Court of Tennessee in Nashville this Certification Order under the seal of this Court along with proof of service.

IT IS SO ORDERED.

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KEVIN H. SHARP
UNITED STATES DISTRICT JUDGE